

REMARKS

The Official Action dated July 6, 2004 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 1-3, 5-8 and 10 have been amended to refer to an "indicator" rather than a "time indicator". Claim 1 has also been amended to include the limitations of claim 4, and claim 4 has been cancelled. It is believed that these changes do not involve any introduction of new matter and do not raise any new issues after final rejection, whereby entry is believed to be in order and is respectfully requested.

Claim 1-11 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that claim 1 is vague with respect to the placement of the time indicator and it is unclear how the elapsed time is measured. The Examiner referred to the *Webster's Dictionary* definitions of "time" and "indicator" and asserted that the indicator recited in the instant claims does not measure time but rather indicates the end of the assay has been reached.

This rejection is traversed and reconsideration is respectfully requested. While it is believed that the phrase "time indicator" as used in the previous claims and the specification is clear to one of ordinary skill in the art, the present claims have been amended to refer to an "indicator" rather than "time indicator." Thus, the claims are further clarified to avoid any implication that the indicator displays an elapsed period of time in minutes or the like.

Thus, claims 1-3 and 5-11 particularly point out and distinctly claim the subject matter which Applicants regard as the invention in accordance with the requirements of 35 U.S.C. §112, second paragraph. It is therefore submitted that the rejection has been overcome, and reconsideration is respectfully requested.

Claims 1-4, 10 and 11 were rejected under 35 U.S.C. §102(b) as being anticipated by the May et al U.S. Patent No. 5,602,040. Claims 7-9 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over May et al. The Examiner asserted that May et al teach a device embodiment containing a control zone loaded with an antibody that will bind to a labeled antibody from a first zone or containing an anhydrous reagent that, when moistened, produces a color change or color formation. The Examiner further asserted that May et al teach the use of an absorbent sink and that the time indicator taught by May et al is located directly on the wicking member or is located on the wicking member and the wicking member is disposed on a test strip.

However, Applicants submit that the assay devices and methods defined by claims 1-3 and 7-11 are neither anticipated by nor rendered obvious over May et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, according to claim 1, the assay device of the present invention comprises an elongate flow matrix, a wicking member, an indicator, and a housing. The elongate flow matrix allows lateral transport of fluid therethrough by capillary action and comprises a liquid application zone and a detection zone downstream of the liquid application zone. The detection zone has an immobilized capture agent capable of directly or indirectly binding to an analyte in an aqueous sample. The wicking member is at the downstream end of the flow matrix and has an upstream end and a downstream end. The indicator is downstream of the detection zone for indicating when liquid applied in the liquid application zone has reached the indicator. The indicator comprises an indicator substance or substance combination which is capable of exhibiting a visible color change when hydrated by the aqueous sample. The indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends, thereby permitting variation of the time elapsing from the application of liquid to the liquid application zone until the indicator

substance or substance combination changes color. The housing encloses the flow matrix and the wicking member, and the indicator is included on an inner side of the housing at a transparent or translucent portion thereof. Thus, the assay device is adaptable for use in different assays requiring different liquid travel times by placing the indicator at a desired position between the upstream and downstream ends of the wicking member along the translucent/transparent portion of the housing.

May et al disclose an analytical test device which, as described at column 5, beginning at line 8, may include a control zone to convey an unrelated signal to the user that the device has worked. May et al disclose that the control zone can be loaded with an antibody that will bind to the labeled antibody or may contain an anhydrous reagent that, when moistened, produces a color change or a color formation. Further, the control zone could contain immobilized analyte which will react with excess labeled reagent. May et al disclose that the control zone is visible through a window, for example window 205 in the embodiment of Fig. 6, the aperture 509 in the embodiment of Fig. 8, or the aperture 604 in the embodiment of Fig. 11.

However, Applicants find no teaching or suggestion by May et al that the control zone may be variably arranged downstream of a flow matrix or a detection zone. Importantly, Applicants find no teaching or suggestion by May et al that any portion of the housing should be formed with a transparent or translucent portion, particularly where an indicator is located on an inner side of the housing at the transparent or translucent portion thereof, as required in the assay device of claim 1. To the contrary, May et al teach away from such an assay device in the figures which show casings with a relatively small control zone window 205 (Fig. 6), 509 (Fig. 8) and 604 (Fig. 11), without any teaching of means for viewing an indicator placed anywhere other than at the casing window.

On the other hand, in the assay device of the present invention, wherein the indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends thereof, and at a translucent/transparent portion of the housing, the indicator has a wide range of positions along the wicking member, visible through the translucent/transparent housing portion. For example, with reference to Fig. 3, the position of the indicator 14 may be varied along the length of the wick 13 as desired depending on the particular assay which is to be conducted. Applicants find no teaching or suggestion by May et al in this regard.

In the Official Action, the Examiner asserted that May et al teach laminating the porous carrier to a transparent moisture-impermeable plastic material and that the transparent strip is in contact with the upper inner surface of the casing, referring to column 14, lines 33-41. The transparent plastic sheet 607 of May et al is disclosed as providing a seal against apertures 603 and 604 to prevent ingress of moisture or sample into the casing. Thus, the teaching by May et al of a transparent plastic sheet 607 does not teach or suggest a device as presently claimed including a housing having a transparent or translucent portion thereof which allows variable positioning of an indicator on a wicking member.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the failure of May et al to teach an indicator arranged in contact with a wicking member at a variable position, in combination with a housing having a translucent or transparent portion at which the indicator is arranged, May et al do not disclose each and every element as set forth in the present claims. Thus, May et al do not anticipate the present claims under 35 U.S.C. §102.

Moreover, it is error to find obviousness where references diverge from and teach away from the invention at hand, *In re Fine*, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988). As

May et al fail to teach or suggest varying the position of the control zone or any element therein, particularly at a location wherein the housing is provided with a translucent or transparent portion, and rather teach a control zone at a set window or aperture location, May et al teach away from the presently claimed assay device. Thus, May et al do not render the present claims obvious.

It is therefore submitted that the assay device and methods defined by claims 1-3, and 7-11 are neither anticipated by nor rendered obvious over May et al, whereby the rejections under 35 U.S.C. §§ 102 and/or 103 have been overcome. Reconsideration is respectfully requested.

Finally, claims 5 and 6 were rejected under 35 U.S.C. §103(a) as being unpatentable over May et al in view of the Gattiglia U.S. Patent No. 6,655,315. The Examiner asserted that it would have been obvious to use an indicator label-soaked support as taught by Gattiglia in the device of May et al.

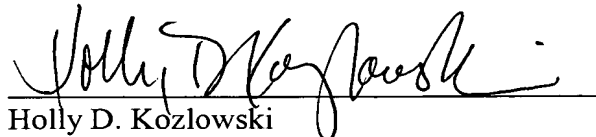
However, Applicants submit that the assay devices defined by claims 5 and 6 are nonobvious over and patentably distinguished from the combination of May et al and Gattiglia. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The deficiencies of May et al with respect to claim 1, from which claims 5 and 6 depend, are discussed in detail above. These deficiencies apply equally as well to the devices defined by claims 5 and 6 which respectively recite that the indicator includes a hygroscopic substance and a filler substance. The deficiencies of May et al are not resolved by Gattiglia. That is, Gattiglia discloses moisture indicators which comprise copper chloride or another salt capable of releasing copper and chloride ions, and synergistic salts containing chloride ions which may be hygroscopic on a suitable support. The support may be an amorphous silica or silica gel, a solid paper support, or a bentonite or calcium sulfate for making pellets.

However, Applicants find no teaching or suggestion or Gattiglia relating to an assay device as presently claimed, particularly including a flow matrix, a wicking member, an indicator and a housing as recited in claim 1, wherein the indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends thereof and on an inner side of the housing at a transparent or translucent portion thereof. In fact, Applicants find no teaching or suggestion by Gattiglia relating to assay devices or housings suitable for use therein. Thus, Gattiglia does not resolve the deficiencies of May et al, whereby the devices of claims 5 and 6 are nonobvious over and patentably distinguishable from the combination of May et al in view of Gattiglia. It is therefore submitted that the rejection of these claims under 35 U.S.C. §103 has been overcome. Reconsideration is respectively requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 102, 103 and 112, second paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested. In the event that the present application is still not in condition for allowance, entry of the present Amendment for purposes of appeal is requested.

Respectfully submitted,



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